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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/795,880	03/08/2004	Regis W. Haid JR.	4002-3436/PC853.00	2119
52196	7590	04/05/2006		
KRIEG DEVAULT LLP ONE INDIANA SQUARE, SUITE 2800 INDIANAPOLIS, IN 46204-2709			EXAMINER KIM, JOHN	
			ART UNIT	PAPER NUMBER

3733

DATE MAILED: 04/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/795,880	<b>Applicant(s)</b> HAID ET AL.	
	<b>Examiner</b> John Kim	<b>Art Unit</b> 3733	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 March 2006.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) 3-7 and 41-54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 8-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 March 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/8/04, 8/15/05</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of invention I (claims 1-40) and specie B (figure 7) in the reply filed on 3/22/06 is acknowledged.

Claims 3-7 and 41-54 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 3/22/06. The pending claims are 1, 2, and 8-40.

### ***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the first and second positions (as stated in claims 10, 25) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for

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consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Claim Objections***

In claims 17-19, 22, 26, 35-37, 40, there exists an inconsistency between the language in the preamble and that of the body of the claim, thus making the scope of the claim unclear. In the preamble, line 1, applicant recites "a spinal stabilization system", indicating that the claim is directed to the subcombination, "a spinal stabilization system". However, applicant positively and functionally recites (in the independent claim) the patient's bone, i.e. "for positioning through a pathway... into the adjacent bony structure", thus indicating that the combination, system and pathway into the adjacent bony structure, is being claimed. As such, it is unclear whether applicant intends to claim the subcombination or combination. Since claiming the combination of the system and pathway into the adjacent bony structure makes such claim(s) directed to non-statutory subject matter, applicant should amend the claims so as to remove all positive recitations of the pathway into the adjacent bony structure. As such, the claim(s) would be directed to the subcombination, the system, and will be considered as such for examination purposes.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 23, 28, 29 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "adjacent articular surfaces" in line 4. There is insufficient antecedent basis for this limitation in the claim.

Claim 23 recites the limitation "said flexible inner member" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claims 28 and 29 recites the limitation "insertion pathway" in line 4 and line 2, respectfully. There is insufficient antecedent basis for this limitation in the claim. It is noted that a "pathway" is claimed in 25, however, applicant switches between pathway and insertion pathway. Examiner asks to be either consistent with the limitation or present "insertion pathway" properly, if separate from pathway.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 2, 8-22, 25-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Livingston (US Pat 2699774).

Livingston discloses the claimed invention of an elongated stabilization device with a longitudinal axis, a length, a cross-section, and a curved configuration (see figure 7 where device is circular along the longitudinal axis) (claim 1, 25), a rigid rod (claim 2), elongated outer member (19), elongated inner member (claim 8, 25), both with tapered ends at both ends of each member (claim 9, 27), where the inner member can inserted to the second position where the outer member is expanded to engage bony tissue (see figure 6) (claim 10, 11, 20, 21, 28, 29, 38, 39), inner member has leading end nose (38) and outer member has inner surface (35) with a tapered portion (36) (col 2:32-81) (claim 12, 30), inner member has a enlarged trailing end (42) and an intermediate nose (41, figure 5) outer member has an enlarged trailing end portion (30) (claim 13, 16, 31, 34), inner member has a threaded portion (40) (claim 14, 32), intermediate and leading end nose engages inner surface of outer member (see fig 6) (claim 15, 33).

In regards to claims 17-19, 22, 26, 35-37, 40, as noted in the objection above, will be treated to focus on the subcombination, the system. While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. (See MPEP 2114). Any statement of intended use and other functional statements do not impose any structural limitations on the claims and are not distinguishable over Livingston, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ

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458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Livingston (US Pat 2699774) as applied to claim 1 above, and further in view of Kashuba et al (US Pat 5908423, in the IDS).

Livingston discloses the claimed invention except for having a drill instrument. Kashuba discloses a drill instrument (figure 3,4) with an outer shaft (22) with a passage, a cutting device (18) and a coupling member (16) and a curved configuration (figure 4). The drill would make a passage for the device. It would have been obvious to one skilled in the art at the time the invention was made to construct the invention of

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Livingston including a drill instrument in view of Kashuba in order to make a pathway for the stabilization device.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Livingston (US Pat 2699774) as applied to claim 1 above, and further in view of Foley et al. (US Pat Pub 2002/0161368).

Livingston discloses the claimed invention except for having an insertion instrument and a pair of anchors. Foley discloses an insertion instrument (20) and a pair of anchors (60 a,b). This allows an easier insertion for the device. It would have been obvious to one skilled in the art at the time the invention was made to construct the invention of Livingston including an insertion instrument and a pair of anchors in view of Foley in order to make insertion easier.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892 for art cited of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is (571) 272-2817. The examiner can normally be reached on M-F 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JK



  
EDUARDO C. ROBERT  
SUPERVISORY PATENT EXAMINER